

Atty. Docket No.: 364106/0176

SBP:DMF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: George S. Gabriel et al.

Serial No.: 09/173,134

Art Unit: 3643

Filed: October 15, 1998

Examiner: Son T. Nguyen

For: MULTISPECIES RODENT CAGE

January 28, 2002

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DECLARATION OF BETTY FATZIE

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Declaration is submitted by the undersigned, Betty Fatzie, who makes the following Declaration:

1. I am currently Executive Vice President of Sales at Lab Products, Inc. (LPI), Assignee of Record of the above-identified application. I have been involved continuously in the marketing and sale of laboratory animal cages and systems for LPI for over twenty-five years.
2. In 1998, LPI introduced to the public the One Cage™ System, a multipurpose cage level barrier rodent cage for housing multiple species of rodents. LPI began selling the One Cage™ System to the public in 1999.
3. Each cage level barrier rodent cage of the One Cage™ System is covered by claims 1 and 2 of the above-identified patent application. By that I mean a cage level barrier rodent cage of the One Cage™ System has a floor with a footprint with an area of 80 square inches.

4. Each One Cage™ System (including a cage level barrier rodent cage and a rack) is covered by claims 3-6 of the above-identified patent application. By that I mean each cage level barrier rodent cage of the One Cage™ System has a floor with a footprint with an area of 80 square inches, and each rack has a depth that is less than or equal to 36 inches. Advantageously, that rack depth enables the One Cage™ System to fit through a standard commercial doorway (typically measuring 37.5" from door-jam to door-jam).

5. At the time LPI introduced the One Cage™ System in 1998, LPI was not aware of any other cage level barrier rodent cage which had a floor with a footprint of 80 square inches that could house any of a plurality of rodent types (e.g., rats, mice, hamsters and guinea pigs) and that met ILAR standards for each rodent type.

6. LPI is currently not aware of any other cage level barrier rodent cage which has a floor with a footprint of 80 square inches that can house any of a plurality of rodent types (e.g., rats, mice, hamsters and guinea pigs) and that meets ILAR standards for each rodent type.

7. At the time LPI introduced the One Cage™ System in 1998, LPI was not aware of any other rodent housing system having a cage level barrier rodent cage which had a floor with a footprint of 80 square inches and a rack with a depth that is less than or equal to 36 inches, and that could house any of a plurality of rodent types (e.g., rats, mice, hamsters and guinea pigs) and that met ILAR standards for each rodent type.

8. LPI is currently not aware of any other rodent housing system having a cage level barrier rodent cage which has a floor with a footprint of 80 square inches and a rack with a depth that is less than or equal to 36 inches, and that can house any of a plurality of rodent types (e.g., rats, mice, hamsters and guinea pigs) and that meets ILAR standards for each rodent type.

9. At the time LPI began selling the One Cage™ System in 1999, LPI was selling numerous other cage level barrier rodent cages and systems under the brand names MOUSE MICRO ISOLATOR SYSTEM, LOW PROFILE MOUSE MICRO ISOLATOR SYSTEM, RAT MICRO ISOLATOR SYSTEM, LARGE MOUSE MICRO ISOLATOR SYSTEM, HAMSTER MICRO ISOLATOR SYSTEM, GUINEA PIG MICRO ISOLATOR SYSTEM, SUPER MOUSE MICRO ISOLATOR SYSTEM, and SUPER MOUSE 750 MICRO ISOLATOR SYSTEM. Each of these various cage level barrier rodent cages and systems are intended for use with a single, specific rodent type, and each is sized to house a single specific rodent type or a plurality of that specific rodent type, and to meet ILAR standards.

10. As previously stated, LPI sold the first One Cage™ System in 1999. In the first three years after its introduction, gross sales for the One Cage™ System for the period 1999-2001 were \$9,430,000. That represents 24% of LPI's gross sales for the period 1999-2001 for all its cage level barrier rodent cages and systems.

11. Thus, despite the fact that, in 1999, LPI already offered and sold a plurality of cage level barrier rodent cages and systems, each sized and shaped for a particular rodent type (and rodent size), LPI's introduction in 1998, and first sales in 1999, of the One Cage™ System was hugely successful and immediately displaced sales for LPI's existing cage level barrier rodent cages and systems.

12. One reason for this immediate commercial success is the fact that LPI's One Cage™ System satisfied a particular need for certain customers because the One Cage™ System eliminates the need for a laboratory to purchase and inventory a plurality of cage and rack sizes for distinct types (species) of rodents. For example, the approximate cost of a single LPI cage

level barrier rodent cage system for mice only is \$45,000. The approximate cost of a single LPI cage level barrier rodent cage system for rats only is \$25,000. The approximate cost of a single LPI cage level barrier rodent cage system for guinea pigs only is \$25,000. The approximate cost of a single LPI cage level barrier rodent cage system for hamsters only is \$25,000. A customer would have to spend approximately \$120,000 to purchase four separate cage level barrier rodent cage systems necessary to house rats, mice, guinea pigs and hamsters. The cost of a comparably equipped One Cage™ System (a rack, cages and feeders that could accommodate mice, rats, guinea pigs and hamsters) is approximately \$35,000. Thus, because of LPI's introduction of the One Cage™ System, a customer's cost to purchase the cage level barrier rodent cage systems necessary to house mice, rats, guinea pigs and hamsters has been reduced by approximately \$85,000, for a comparable system.

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inventor's
opinion as to
why purchaser
buying the
product is
insufficient*

13. Another reason for the immediate commercial success of LPI's One Cage™ System is that it provides customers with the ability to standardize the size of their cage level barrier rodent cages and systems. That significant improvement over prior art cages and systems results in more efficient use of valuable laboratory space and simplifies facilities planning and design. Prior art cage level barrier rodent cages and systems have different cage and rack footprints for different rodent types. Thus, a mice-only cage and system takes up a different amount of laboratory and inventory space than a rat-only cage and system. Consequently, it is difficult to plan and make efficient use of valuable laboratory and inventory space because the type of rodent being evaluated (and thus the size of the cage and system required) is subject to change. LPI's One Cage™ System advantageously provides a single rack footprint for a plurality of rodent types, while meeting ILAR standards. That unique and advantageous feature

provides for more efficient utilization of laboratory floor space, and facilitates planning for future floor spaces needs because customers need not be concerned with different size cage and racks for different rodent types. Regardless of the type of rodent being evaluated, the size of the cages and racks does not change. In addition, the standardized cage and rack size provided by LPI's One Cage™ System enables customers to reduce their inventory requirements because a single size cage level barrier rodent cage may now be inventoried, instead of a different cage for each rodent type.

14. Still another reason for the immediate commercial success of LPI's One Cage™ System is that it eliminates the inefficiency that occurs during cleaning, sorting and delivering the various different size and shape cage level barrier rodent cages when transitioning from one study to the next, or in the ordinary course of cleaning the cages during a particular study. For example, during a study, each rodent cage must be disassembled, cleaned, reassembled, fitted in an appropriate rack, and delivered to the laboratory where it is next needed. It should be noted that a typical cage level barrier rodent cage includes a cage bottom, wire lid, top, feeder, water bottle, and other components that are all uniquely suited for a particular rodent type. Those various components are not interchangeable from one rodent cage or system to another. All of these various component parts of the rodent cage are cleaned many times during a study. The various different size rodent cages are typically delivered to a cleaning room, where a technician will perform the steps necessary to ensure proper cleaning of the rodent cages. From the illustrative list provided above in paragraph 9, it can be seen that the number of different type and size rodent cages presents a significant burden on the cleaning room technicians to sort, reassemble, and deliver the proper rodent cage (and its component parts) to the proper laboratory

for the next study. In some cases, a test facility will have multiple laboratories located on different floors and possibly in different buildings, further exacerbating the burden on the cleaning room technician. LPI's One Cage™ System provides a single cage level barrier rodent cage and rack that virtually eliminates the undesirable shortcomings described above. Sorting of the various rodent cages (and their respective component parts) is eliminated during cleaning, as the same cage level barrier rodent cage and rack may be used to house a plurality of different rodent types. Reassembly is significantly simplified as the cleaning room technician need not be concerned with matching the various component parts of the rodent cage. With LPI's One Cage™ System, a single cage level barrier rodent cage and rack replace the various different cage level barrier rodent cages and racks previously required for the different rodent types. Thus, LPI's One Cage™ System provides a single cage level barrier rodent cage and rack that may be used for any of a mice, rat, guinea pig or hamster, with standardized component parts (including a cage level barrier rodent cage and rack).

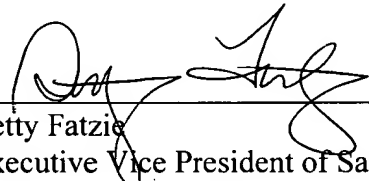
15. One customer that recognized and benefited from the unique advantages provided by LPI's One Cage™ System is Advance Medicine, Inc. In 1999, Advanced Medicine purchased 10 One Cage™ Systems. As evidenced by the Declaration of Dietrich Crase, Associate Director of Pharmacology for Advanced Medicine (filed concurrently herewith), the One Cage™ System solved myriad problems for Advanced Medicine. For example, the unique size of the One Cage™ System (i.e., the floor of the cage having an area of 80 square inches while still meeting all ILAR requirements for the plurality of rodent types housable within the One Cage™ System) enabled Advanced Medicine to accommodate different rodent species in the same rack, and to reduce the inventory of different cage types. The standardize caging

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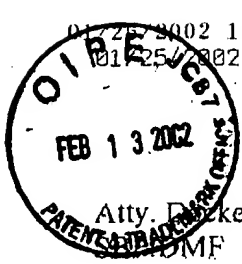
provided by the One Cage™ System greatly enhanced Advanced Medicine's efficiency and space utilization in their laboratory.

16. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 1/25, 2002



Betty Fatzie
Executive Vice President of Sales



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DECLARATION OF DIETRICH CRASE

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Declaration is submitted by the undersigned, Dietrich Crase, who makes the following Declaration:

1. I am currently Associate Director of Pharmacology at Advanced Medicine, 901 Gateway Boulevard, South San Francisco, California 94080. I have held that position since 1998. I have no financial interest in Lab Products, Inc. (LPI), or in any entity related thereto or affiliated therewith

2. As Associate Director of Pharmacology, my responsibilities include the selection and purchase of laboratory equipment, including rodent cages and systems.

3. Advanced Medicine's laboratory is relatively small with limited storage space. Despite those physical limitations, our laboratory has very high throughput. By that I mean that we conduct a substantial amount of animal evaluations and testing on a variety of animal types. Most of our animal evaluations and testing are conducted on rodents; namely mice and rats.

Consequently, we frequently must reconfigure our laboratory space to accommodate a different

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rodent type upon completion of one test. It is thus necessary for us to inventory rodent cage and rack systems for each rodent type that may be subject to evaluation or testing in our laboratory.

4. At least before 1999, Advanced Medicine was purchasing a variety of different sized rodent cages and systems from various suppliers to accommodate a variety of different rodent types and sizes. One of the various suppliers was LPI.

5. In or around 1999, Advanced Medicine decided to incorporate into its operations a rodent caging system that would allow maximum versatility, while at the same time employing a minimum number of components, sizes, styles, etc. Also in or around 1999, Advanced Medicine became aware of the One Cage™ System being offered for sale by LPI. At that time, Advanced Medicine could find no other cage level barrier rodent cage available from any supplier other than LPI that would satisfy Advanced Medicine's rodent caging system needs.

6. LPI's One Cage™ System met Advanced Medicine's rodent caging system needs (see number 5, above) exceedingly well and enabled Advanced Medicine to accommodate different rodent species (i.e., sizes) in the same room, even on the same rack, with the additional benefit of reducing inventory of cage types.

7. The "standardized caging" provided by LPI's One Cage™ System has greatly enhanced Advanced Medicine's efficiency and laboratory and storage space utilization.

8. The benefits recognized by Advanced Medicine, as set forth in paragraphs 6 and 7 above, are due to the ability of LPI's One Cage™ System to accommodate a plurality of rodent types, and to its unique size and proportion, specifically, to the fact that the cage level barrier rodent cage of the One Cage™ System has a floor with a footprint with an area of 80 square

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inches. Moreover, the One Cage™ System meets ILAR requirements for each rodent type housable within the One Cage™ System.

9. Since LPI's introduction of its One Cage™ System, Advanced Medicine has not found any other cage level barrier rodent cage of the One Cage™ System has a floor with a footprint with an area of 80 square inches, and that can accommodate a plurality of different rodent types, while meeting ILAR requirements for each rodent type, as can the One Cage™ System.

10. One reason Advanced Medicine selected and continues to purchase LPI's One Cage™ System is the cost savings we realize by not having to purchase and inventory different cage level barrier rodent cages and systems for our different rodent type needs. We can now purchase a single cage level barrier rodent cage and system for all of our rodent types.

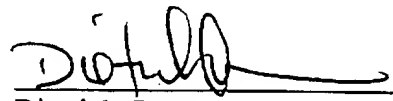
11. Another reason Advanced Medicine selected and continues to purchase LPI's One Cage™ System is that it provides us with the ability to standardize the size of our cage level barrier rodent cages and systems. We have been able to significantly improve our use of laboratory and inventory space as a result of the standardized cage and rack footprint provided by the One Cage™ System. We have also been able to more easily transition from evaluating or testing different rodent types. I believe that the One Cage™ System is a significant improvement over other commercially available cage level barrier rodent cages and system because it results in a more efficient use of valuable laboratory space and simplified facilities planning and design.

12. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these

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statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: January 25, 2002


Dietrich Crase
Associate Director of Pharmacology